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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Young et al.

Confirmation No.: 3847

Serial No.: 09/999,265

Art Unit: 1648

Filed: November 28, 2001

Examiner: Brown, Stacy S.

For: METHODS OF
ADMINISTERING/DOSING
ANTI-RSV ANTIBODIES FOR
PROPHYLAXIS AND
TREATMENT

Attorney Docket 10271-048
No:

PROVISIONAL ELECTION UNDER 37 C.F.R. § 1.143 WITH TRAVERSAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement, mailed March 4, 2003, and in accordance with Rule 143 of the Rules of Practice, please consider the following remarks. Applicants submit herewith a Petition for Extension of Time (in duplicate) for responding to the Restriction Requirement, accompanied by a provision authorizing payment of the required fee.

It is estimated that no additional fee is required for filing this response. In the event that an additional fee is required, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

REMARKS

Claims 1-127 are pending in this application. The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-40 and 53-127, drawn to a method of preventing, treating or ameliorating an RSV infection, classified in class 435, subclass 5.
- II. Claims 41-53, drawn to a pharmaceutical composition comprising antibodies that immunospecifically bind to one or more RSV antigens,

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classified in class 424, subclass 130.1.

The Examiner contends that the inventions of Groups I and II are distinct from each other. Applicants hereby elect to prosecute the claims of Group I, claims 1-40 and 54-127, drawn to a method of preventing or treating a RSV infection, without prejudice to Applicants' right to pursue the non-elected subject matter in other applications.

Group I, claims 1-40 and 54-127, are further subject to a restriction which requires Applicants to elect one of the antibodies recited in claims 12, 27, 40, 85 and 121, and to elect one antibody construct (*i.e.*, one sequence from each CDR) recited in claim 111. Applicants respectfully traverse the restriction requirement requiring the election of a particular antibody and the election of particular CDR amino acid sequences. Applicants respectfully assert that a single search would identify any relevant art pertaining to a method of preventing, treating or ameliorating a respiratory syncytial virus (RSV) infection in a mammal comprising administering to said mammal a particular dosing regime of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, regardless of the particular amino acid sequence of the antibody or a CDR thereof. Thus, contrary to the Examiner's contention, Applicants assert that to search and examine the subject matter of the antibodies and CDR sequences together would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, rev. February 2003) states:

If the search and examination of an application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of M.P.E.P. § 803 all the antibodies recited in claims 12, 27, 40, 85, 111 and 121 should be searched and examined together in the subject application.

At a minimum, the requirement to elect a particular antibody should be modified to a species election. Pursuant to M.P.E.P. § 806.04(d), claims 1-11, 1326, 28-39, 53-84, 86-110, 112-120 and 122-127 are generic claims which generically recite antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens. Dependent claims 12, 27, 40, 85, 111 and 121 merely recite specific species of anti-RSV antibodies for use in the methods claimed. Under 37 C.F.R. § 1.146,

[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the

examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.

Thus, under the Rules of Practice, a species election, not further restriction is, at most, the appropriate action in this matter. Accordingly, Applicants respectfully request that the further Restriction Requirement under 35 U.S.C. § 121 of Group I be withdrawn or modified such that all of the antibodies recited in claims 12, 27, 40, 85, 111 and 121 are examined in one application, or at a minimum, that the further Restriction of Group I be modified to be a species election.

In order to be fully responsive, however, Applicants hereby elect to prosecute the anti-RSV antibody A4B4L1 FR-S28R, and the antibody construct comprising SEQ ID NO:10 for VH CDR1, SEQ ID NO: 19 for VH CDR2, SEQ ID NO:20 for VH CDR3, SEQ ID NO:39 for VL CDR1, SEQ ID NO:5 for VL CDR3 and SEQ ID NO:6 for VL CDR3, with traverse, without prejudice to Applicants' right to pursue the non-elected subject matter in related applications.

Entry of the remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Respectfully submitted,

Date: May 5, 2003

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